

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/937,313	BERNDL ET AL.
Examiner	Art Unit	
Micah-Paul Young	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 15 October 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-9 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-9 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

**Acknowledgment of Papers Received:** Response to Office action filed on 5/14/02.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Davis et al (USPN 5,670,158). The reference teaches a compound comprising a carrier polymer (vinylpyrrolidone), and a surface-active agent with an HLB from 6 to 18, preferably 10 – 16, and is a liquid at 37 degrees Celsius. Also the reference teaches that the solid dispersion can be spray-dried (Abstract; col. 4, lin. 36 – 61, col. 5, lin. 9 – 25; col. 6, lin. 35 – 40). These disclosures render the claimed invention anticipated.

3. Claims 1, 3, and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lippmann et al (USPN 4,259,315). Lippmann teaches a controlled release formulation comprising a polymer carrier and a hydrophilic surfactant having an HLB exceeding 10. The polymeric carrier is ethyl cellulose while the surfactant can be selected from the list consisting of polyoxyethylene sorbitan and sodium lauryl sulfate, and those recited in claim 6 (Abstract; col. 5, lin. 4 – 25). These disclosures render the application anticipated.

4. Claim 1, 7, and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Straub et al (USPN 5,853,698). The reference teaches a pharmaceutical composition in powdered form, comprising a polymer carrier and a surfactant namely glycerol-polyoxyethylene ricinoleate. The

reference goes on to teach that the composition can be prepared through a spray-drying procedure (col. 6, lin. 31 – 48; col. 8, lin. 15 – 31; col. 9, lin. 9 – 11). These disclosures along with others render the claimed invention anticipated.

5. Claims 1, 3, 5, and 9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Shalom et al (USPN 5,618,560). The reference teaches a controlled release formulation comprising a polymer carrier an emulsifier having HLB value from 4 to 16, and present in the composition in a concentration between 2% and 50 %. Bar-Shalom also teaches that the composition is prepared through hot-melt extrusion (Abstract; col. 1, lin. 51 – col. 2, lin. 12; col. 5, lin. 21 – 44; col. 11, lin. 57 – col. 12, lin. 5). These disclosures render the claimed invention anticipated.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1- 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (USPN 5,670,158), Lippmann et al (USPN 4,259,315) Straub et al (USPN 5,853,698) and Bar-Shalom et al (USPN 5,618,560) all in view of each other.

As previously discussed in the *102 b* discussion the references disclose essential elements of the claims intention. Each reference teaches the combination of a polymer, surface-active

surfactant in a solid powdered form, though the ultimate form of the compositions may vary.

Davis combines a polymer with a surfactant with an appropriate HLB; Lippmann teaches the combination of carrier polymers with ethoxylated sorbitan fatty acid esters. In addition to teaching the basic theory of combing a carrier polymer and a surface-active agent, Straub and Bar-Shalom also teach that these combinations can be prepared though spray-drying or melt extrusion processes.

One of ordinary skill in the art would have been motivated to combine any of the polymer carriers of Davis, Lippmann with the process of Straub or Bar-Shalom. Substituting the surface-active agents of Davis and Lippmann into each other would provide sufficient lubrication to a composition. Processing the compound according to Straub would provide increased particle dispersion, while processing according to Bar-Shalom would allow for an increase in uniformity of the compound. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the art as such with an expected result of a powdered, well-lubricated and uniform, excipient comprising a polymer carrier of some kind and an appropriate surface-active agent able to carrier water-insoluble or soluble agents.

***Response to Arguments***

9. Applicant's arguments filed 10/15/02 have been fully considered but they are not persuasive. Applicant argues that:

- a. Davis et al does not disclose a solid mixture of two excipients.
- b. Lippmann et al does not disclose the making or use of a powderous excipient consisting of two components.

- c. Straub et al discloses a gas-filled compound, which is not what is claimed.
- d. Bar-Shalom does not disclose a process for making an excipient by melt extrusion and then isolating it into a powderous form.
- e. Since none of the reference teach the elements of the invention one of ordinary skill in the art would not be motivated to combine the art.

With regard to argument a., Davis discloses a solid mixture of drug, polymeric carrier (polyethylene glycol), lipid (with HLB between 10 and 16), and further additives such as polyvinylpyrrolidone (col. 5, lin. 20 – 31; col. 6, lin. 35 – 40; col. 5, lin. 57 – 64).

Regarding argument b., Lippmann discloses capsules containing micro-particles, which are described as free-flowing powder (col. 4, lin. 8 – 28). The powder of the reference comprises a polymeric carrier and a surfactant as a lubricant (col. 6, lin. 4 – 15).

Regarding argument c., Straub does disclose gas-filled composition, yet the claims contain open-ended claim language, which allows for the inclusion of gas-filled compositions. The composition of Straub is a powderous composition comprising a polymer and a surfactant, which is then spray-dried (col. 8, lin. 15 – 31).

10. Regarding argument d., Bar-Shalom discloses a powdered composition comprising a polymer and surfactant being hot melt extruded (col. 11, lin. 57 – 67). Applicant argues that an isolation step is missing yet, this is not a limitation of the originally claimed invention. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a process comprising melt extrusion, isolation into powderous form, and processing into further forms) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations

from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding argument e., as discussed in the 103 a discussion above after reviewing the art, a skilled artisan would be able to combine the reference to achieve the specific limitations of the instant invention. Applicant is reminded that cited prior art does not have to teach every single element of the claimed invention in order to obviate a claim.

### ***Conclusion***

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young  
Examiner  
Art Unit 1615

M. Young  
January 14, 2003

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600



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1	A...	1
2	REM	11

Total number of pages: 12

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